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(54) **SPECIFIC DISPOSABLE GUIDE DEVICE FOR SPINAL SURGERY**

(71) Applicant: **MEDACTA INTERNATIONAL SA**, Castel San Pietro (CH)

(72) Inventors: **Alfonso Fantigrossi**, Castel San Pietro (CH); **Francesco Siccardi**, Castel San Pietro (CH); **Meinrad Fiechter**, Castel San Pietro (CH)

(73) Assignee: **Medacta International SA**, Castel San Pietro (CH)

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Primary Examiner — Christian A Sevilla
(74) *Attorney, Agent, or Firm* — Meunier Carlin & Curfman LLC

(57) **ABSTRACT**

Various implementations relate to a guide device for spinal surgery, comprising: two guide sleeves extending between a proximal end and a distal end for guiding a surgical intervention on a vertebra of a patient; a plurality of support elements, wherein each support element defines a contact area specifically configured for abutting against a portion of a virtual surface reproducing the vertebra of the patient, in a coupling configuration; and at least one junction element joining the two guide sleeves together. Each guide sleeve comprises a respective auxiliary sleeve extending between a proximal end and a distal end, and the proximal end of the auxiliary sleeve is located in proximity to the proximal end of the respective guide sleeve.

15 Claims, 8 Drawing Sheets

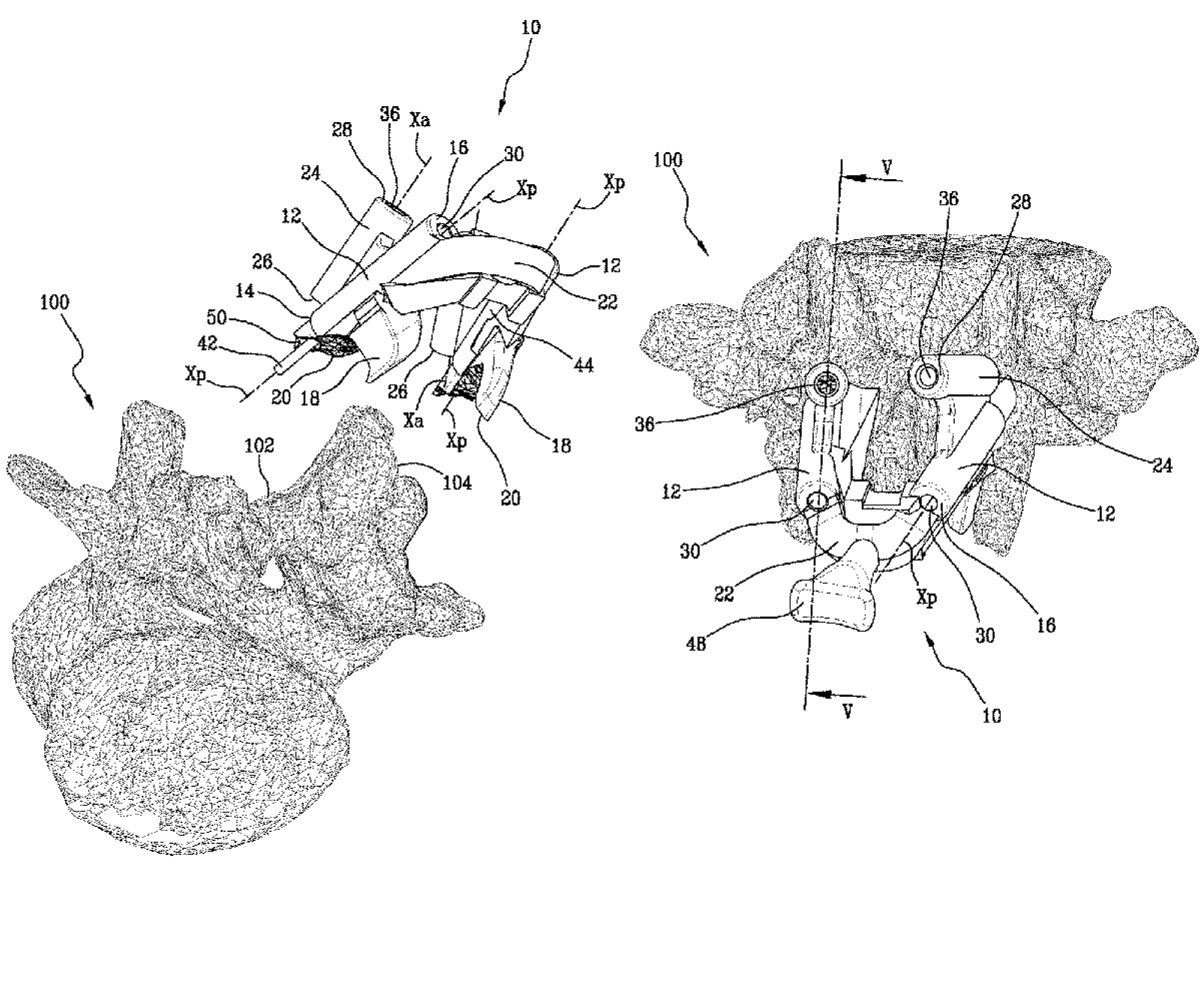

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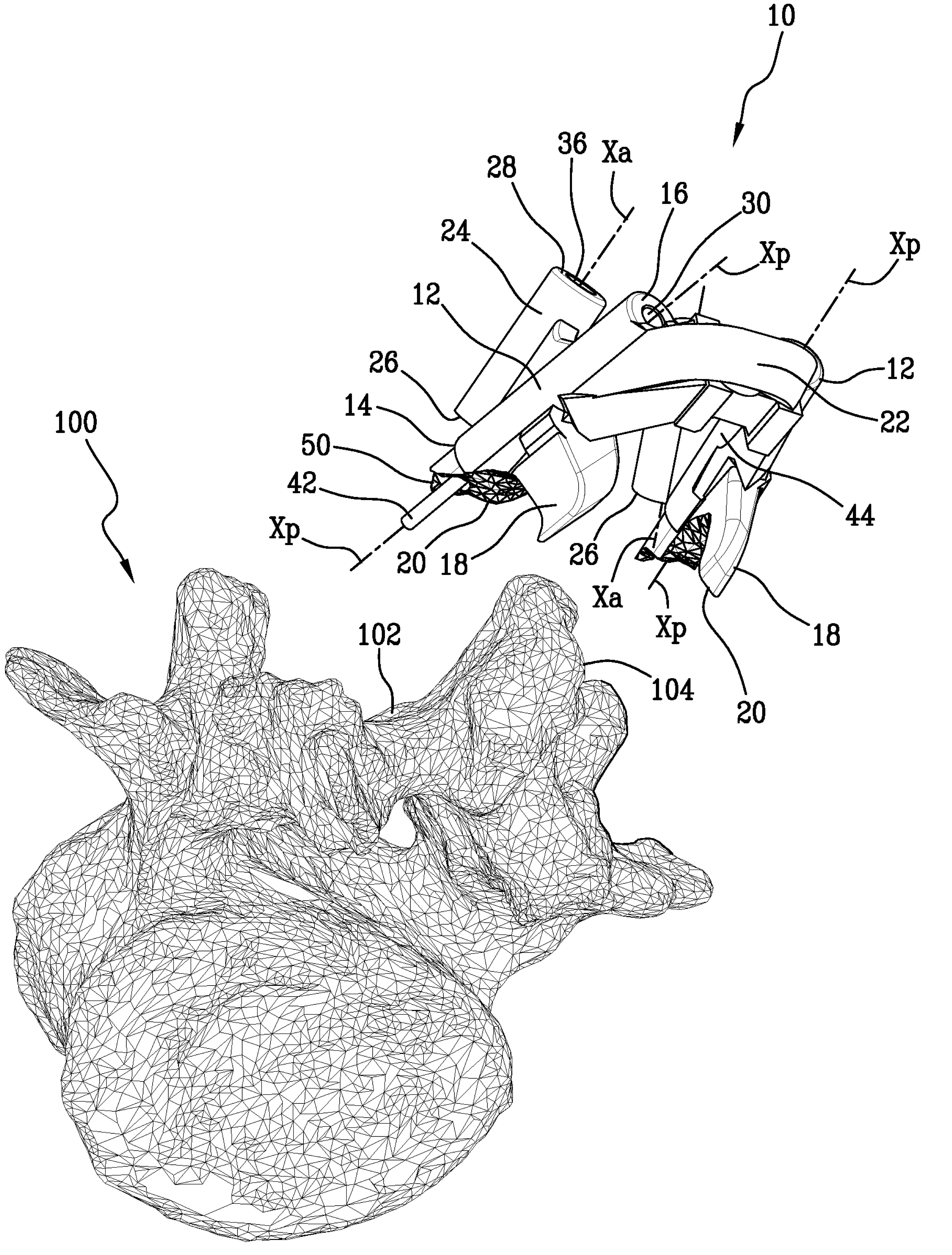
Fig.1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Xa
28
16
30
24
Xp
Xp
12
12
26
22
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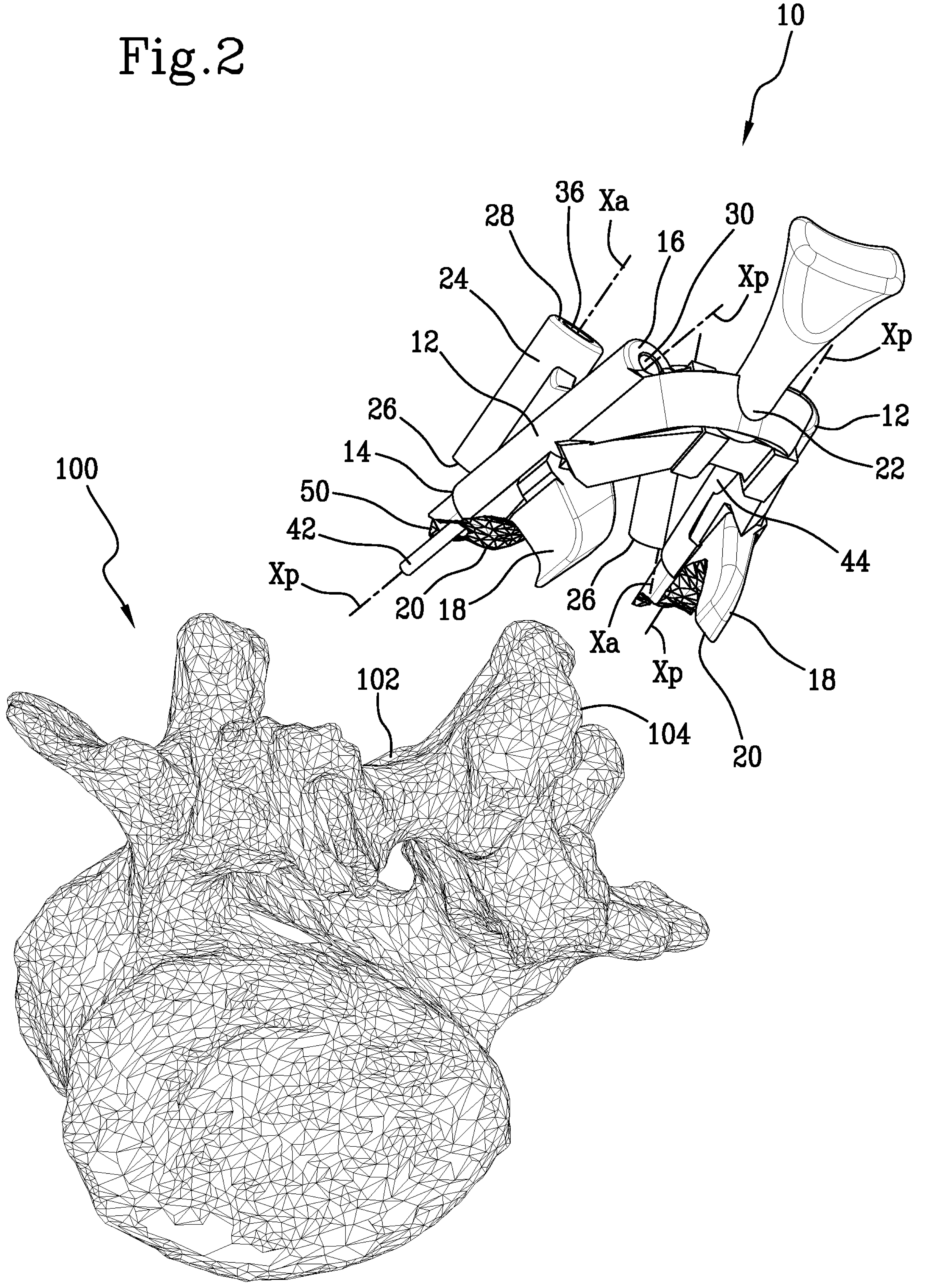
42
Xp
20
18
26
Xa
Xp
18
20
100
102
104

Fig.2


10
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12
12
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Xp
20
18
26
Xa
100
Xp
18
102
104
20

Fig.3

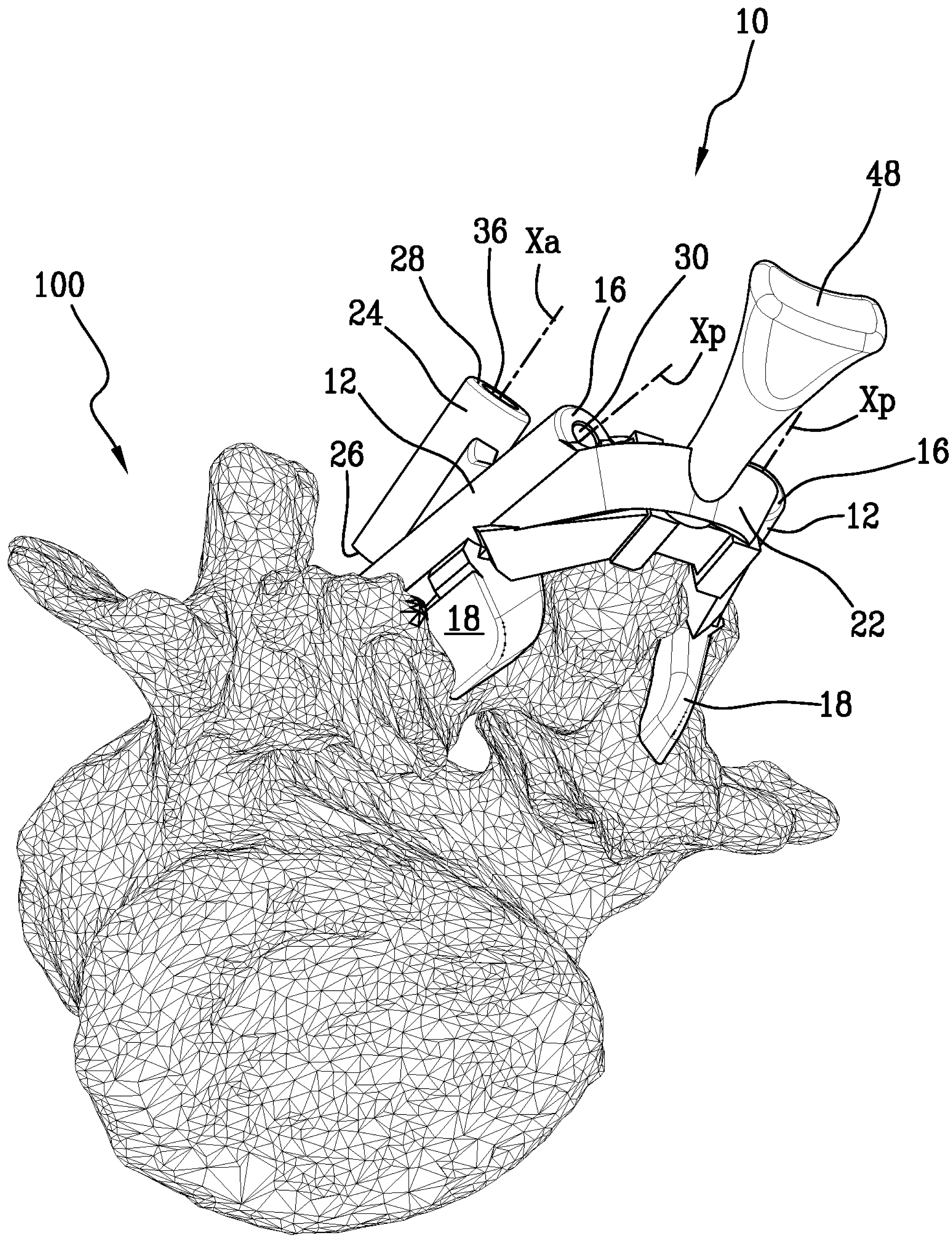
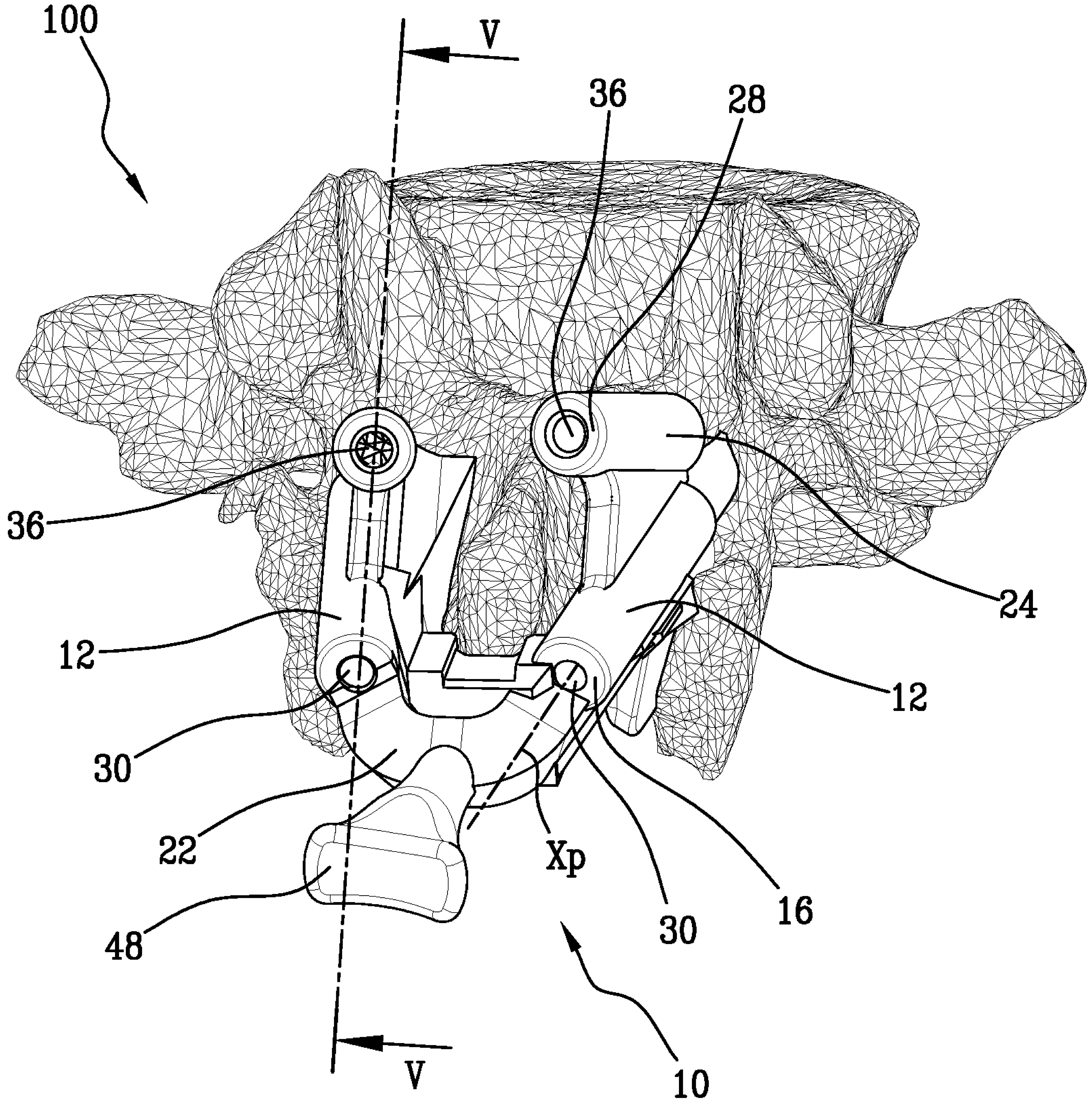


Fig.4



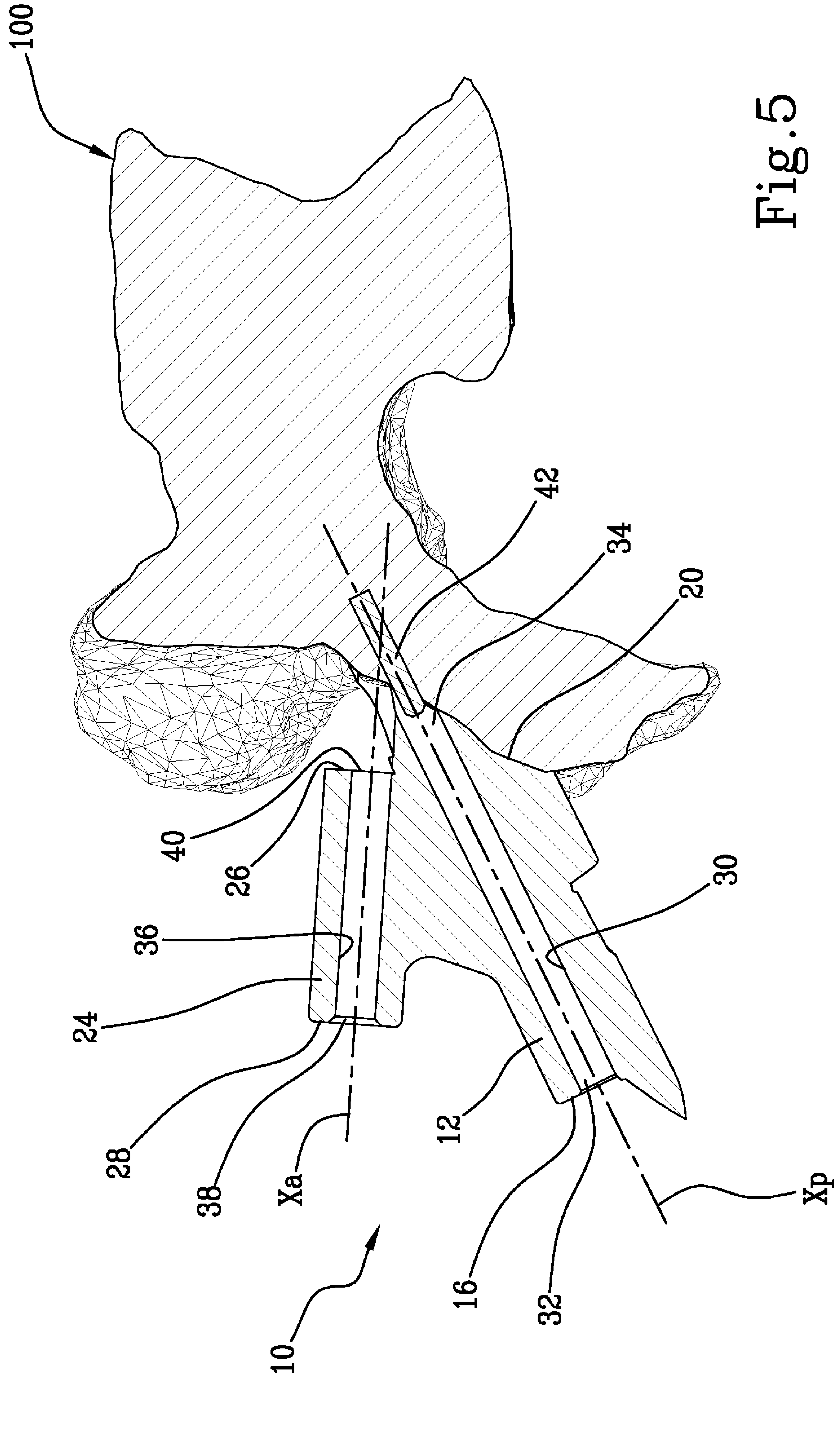


Fig.5

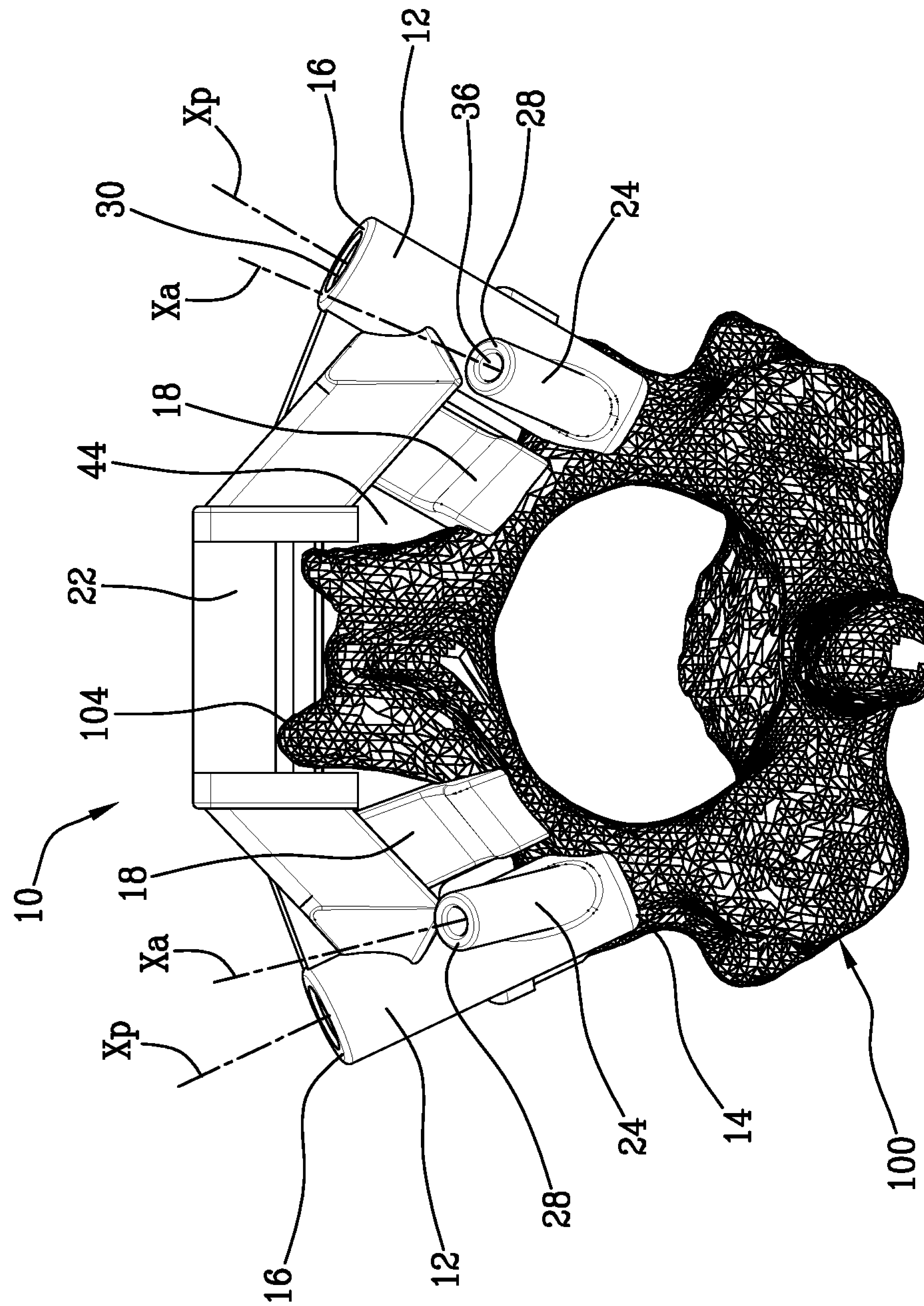


Fig.6

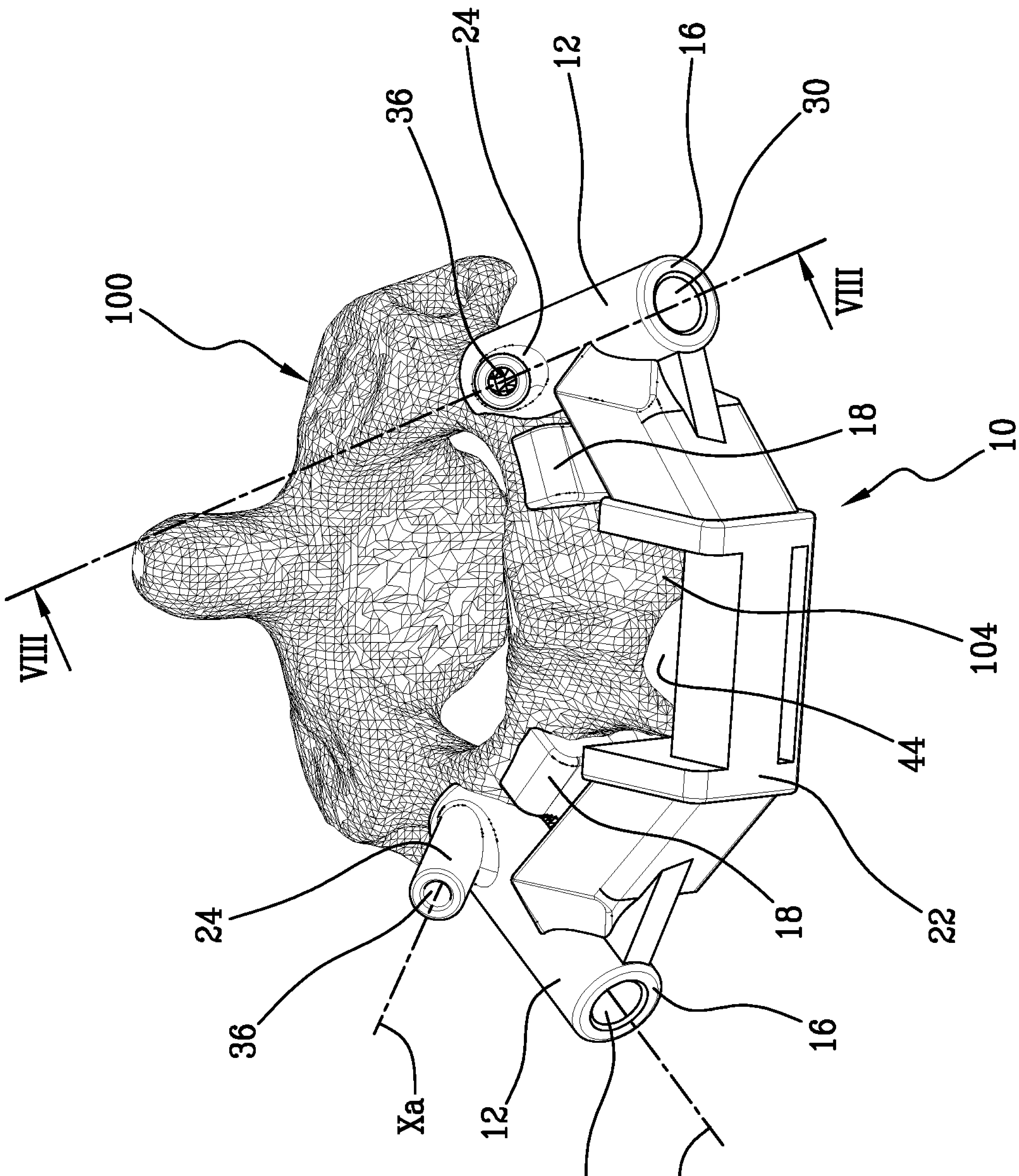


Fig.7

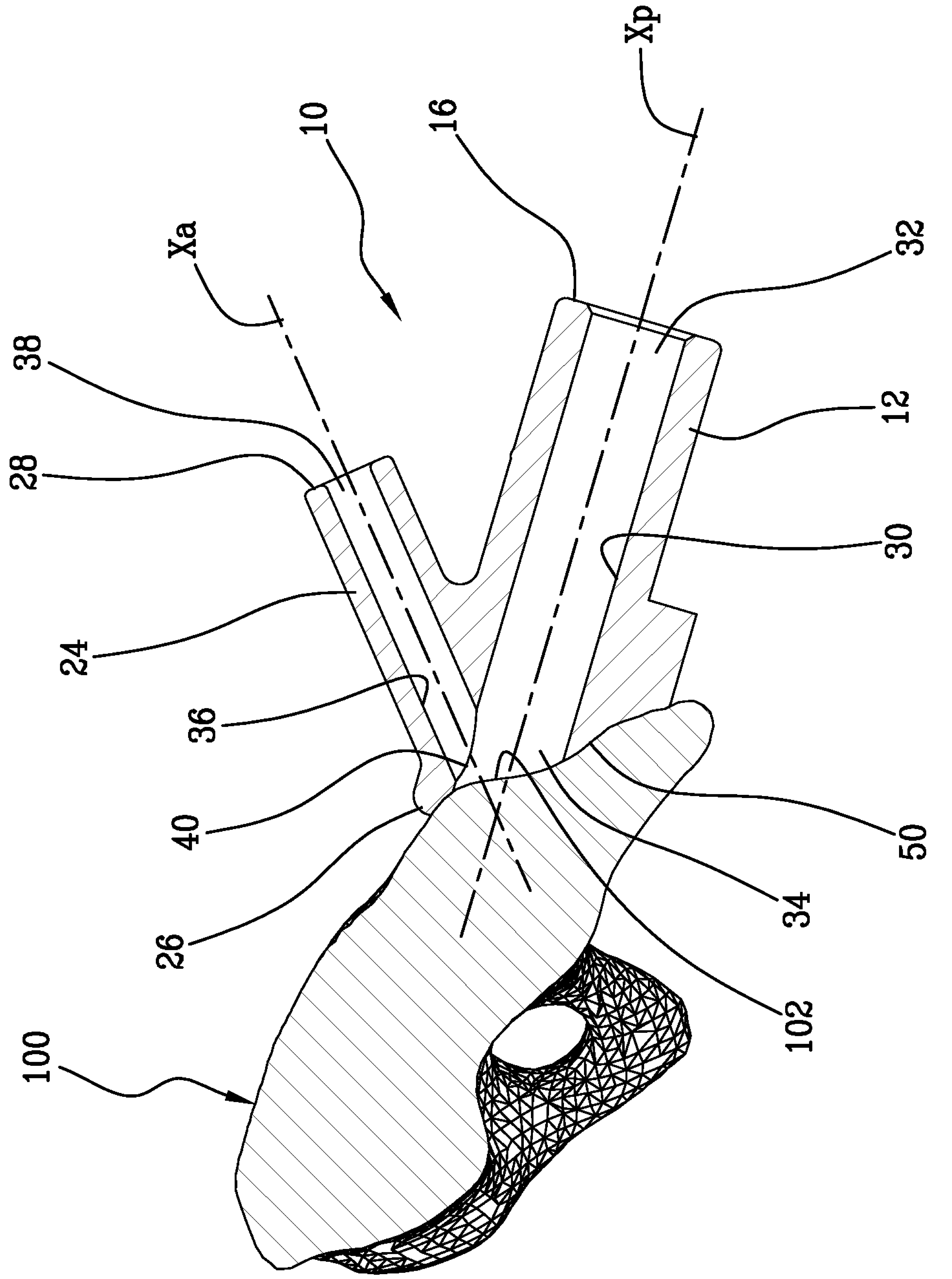


Fig.8

SPECIFIC DISPOSABLE GUIDE DEVICE FOR SPINAL SURGERY

The present invention relates to the technical field of spinal surgery, more specifically it relates to a specific disposable guide device for spinal surgery. This device is used to help the surgeon in the drilling of a vertebra.

Vertebral drilling is often required in the field of spinal surgery, for example for inserting a Kirschner wire, for inserting a guide wire for the application of cannulated screws, or still for inserting solid screws. The drilling direction must be defined with great precision because the hole, which originates on the lamina, must often proceed along a very precise direction, for example along the pedicle of the vertebra. Because of the critical nature of the drilling operation, several solutions have been developed to assist the surgeon.

First of all, techniques have been developed which, through the methods commonly used in diagnostic imaging (for example, computerized tomography), allow digital reconstruction of the specific anatomy of the individual vertebra of the individual patient that must undergo surgery.

The digital model of the individual vertebra allows a physical model to be obtained, on which the drilling is already preoperatively planned in the finest details.

Finally, starting from the vertebra model and the drilling direction deemed optimal by the surgeon, it is possible to construct specific disposable guide devices for drilling. The adjective "specific" as used herein and hereinafter means that the guide device has been customized, or shaped so as to adapt to the anatomy of a specific vertebra of a specific patient.

In this field, guide devices are mainly employed to help the surgeon during pedicle screw insertion, so that the screw can be inserted according to a pre-planned optimal axis of the screw.

However, these devices may be used in spinal surgery for other purposes; for instance, as cutting guides during PSO (pedicle subtraction osteotomies), laminotomy or facetectomies.

In general, guide devices are provided with one or more guide sleeves and one or more contact elements adapted to mate with the vertebrae of the patient in a stable and well-defined configuration.

Guide sleeves define the direction of advancement of the surgical tool. As the skilled person can well understand, in order to faithfully maintain the optimal direction defined during the preoperative phase, the device must absolutely be able to be firmly rested on the vertebra and have a single well-defined position of use easily obtainable in the real operating field.

In order to achieve this goal, a firm contact between the guide device and the patient's bone structure is required.

For optimal positioning of the guide, the surgeon must wash the surrounding tissue away from a large area of the bone, and in some cases cut the ligaments. This operation often proves to be difficult and costly in terms of time and can lead to complications and lengthening of the patient's hospitalization.

Furthermore, the remaining tissue that the surgeon is unable to remove and the surface of the bone itself can lead to slipping and deviation of both the guide device and the tool used for drilling.

If this were to happen, the pedicle screws or bone resections would be positioned incorrectly or sub-optimally.

As mentioned above, the orientation with which the surgical tool reaches the surface of the vertebra, to perforate

it, is defined by the optimal direction the drilling must have with respect to the vertebra. For this reason, the tool may have to reach the surface of the vertebra with a strong inclination that favours undesired displacement thereof, also due to the slippery surface of the vertebra. In this case, therefore, despite the care taken in planning the surgical operation and constructing the guide device, the drilling of the vertebra may be suboptimal.

In view of the foregoing, the technical problem underlying the present invention is to provide a disposable guide device for spinal surgery, which allows the slipping issues on the patient's vertebra to be minimized or prevented.

The aforementioned technical problem is solved by means of a guide device for spinal surgery, according to claim **1**.

More particularly, the aforementioned technical problem is solved by means of a device comprising:

- two guide sleeves extending between a proximal end and a distal end for guiding a surgical intervention on a vertebra of a patient;
- a plurality of support elements, wherein each support element defines a contact area specifically configured for abutting against a portion of a virtual surface reproducing the vertebra of the patient, in a coupling configuration; and
- at least one junction element joining the two guide sleeves together.

Furthermore, each guide sleeve comprises a respective auxiliary sleeve extending between a proximal end and a distal end, and the proximal end of the auxiliary sleeve is located in proximity to the proximal end of the respective guide sleeve.

Advantageously, each guide sleeve and the corresponding auxiliary sleeve have a diverging development starting from the respective proximal ends.

Preferably, each guide sleeve extends along a respective main axis and the respective auxiliary sleeve extends along a respective auxiliary axis. Advantageously, each auxiliary axis intersects the respective main axis.

In accordance with some embodiments of the guide device, each auxiliary axis forms an angle α with the respective main axis. Preferably, the angle α formed by an auxiliary axis and the respective main axis is comprised between 20° and 60°, even more preferably between 25° and 45°.

An insertion duct is located within each guide sleeve and a service duct is located within each auxiliary sleeve.

In some embodiments, the proximal opening of the service duct is defined in the wall of the insertion duct, near its proximal end.

In some embodiments, the proximal opening of the service duct is slightly spaced apart from the proximal opening of the insertion duct.

Both the insertion ducts and the service ducts define respective insertion axes for a surgical tool whose use is preferably planned in detail in the preoperative phase.

The diameter of the insertion duct is such as to allow the insertion of a main surgical tool. Said diameter can be selected from 3-18 mm, 3-12 mm, 3-9 mm, 3-6 mm.

The diameter of the service duct is such as to allow the insertion of a preparatory drill. Said diameter can be selected from 1.8-4 mm, 2-3 mm.

Advantageously, the auxiliary axis reaches the minimum distance from the main axis in proximity to the virtual surface of the vertebra.

Preferably, the auxiliary axis intersects the main axis in proximity to the virtual surface of the vertebra.

Preferably, the auxiliary axis reaches the minimum distance from the main axis or intersects it, at a point inside the vertebra, within 5 mm from the virtual surface.

Advantageously, the guide sleeves can be oriented so that the proximal ends are more distant from each other with respect to the distal ends.

Preferably, each auxiliary axis forms an angle β with the portion of the virtual surface of the vertebra on which it is incident, the angle β being favourable to the use of the preparatory drill.

The angle β is preferably comprised between 60° and 120°, even more preferably between 75° and 105°.

Preferably, the at least one junction element extends transversely to the two guide sleeves to place them in rigid connection with one another. More preferably, the junction element is located in proximity to the distal end of the guide sleeves.

Preferably, the guide sleeves are spaced apart from each other by a distance at least suitable to allow the housing of a spinous process of the vertebra to be operated on.

Preferably, the junction element takes an inverted "U" shape that defines therein a seat for housing the spinous process of the vertebra.

In some embodiments, the seat for housing the spinous process is open in the craniocaudal direction.

Alternatively, the seat for housing the spinous process can be closed in the craniocaudal direction by one or two partitions connecting the sides of the junction element.

Preferably, the junction element comprises a handle suitable to facilitate the surgeon's handling of the device.

Preferably, the support elements, and in particular the respective contact areas, are designed in a patient-specific manner during the preoperative phase.

Preferably, at least one of the support elements is shaped like a hook, so as to at least partially encircle a portion of the vertebra.

Preferably, each guide sleeve is provided with a further own contact portion, near the proximal end, configured for abutting against a portion of the virtual surface of the vertebra.

Further features and advantages of the patient-specific disposable guide device according to the invention will become more apparent from the description, provided hereinafter, of a number of embodiments described by way of non-limiting example with reference to the accompanying drawings, wherein:

FIG. **1** is a perspective view of a disposable guide device according to a first embodiment of the invention;

FIG. **2** is a perspective view of a disposable guide device according to a second embodiment of the invention when it is approached to the respective vertebra;

FIG. **3** shows a view similar to that of FIG. **2** in which the guide device is correctly resting on the respective vertebra;

FIG. **4** shows a different view of the device of FIG. **2** correctly resting on the respective vertebra;

FIG. **5** shows a cross section made along the line V-V in FIG. **4**;

FIG. **6** is a perspective view of a disposable guide device according to a third embodiment of the invention correctly resting on the respective vertebra;

FIG. **7** shows a different view of the device of FIG. **6** correctly resting on the respective vertebra; and

FIG. **8** shows a cross section made along the line VIII-VIII in FIG. **7**.

With reference to the accompanying figures, the numeral **10** indicates a guide device for spinal surgery according to the present invention.

In particular, the figures show the device **10** approached to a specific vertebra **100** for which it was designed and constructed.

The disposable guide device **10** for spinal surgery comprises:

- two guide sleeves **12** extending between a proximal end **14** and a distal end **16** for guiding a surgical intervention on a vertebra **100** of a patient;
- a plurality of support elements **18**, wherein each support element **18** defines a contact area **20** specifically configured for abutting against a portion of a virtual surface **102** reproducing the vertebra **100** of the patient, in a coupling configuration; and
- at least one junction element **22** joining the two guide sleeves **12** together.

In the disposable guide device **10** according to the invention, each guide sleeve **12** comprises a respective auxiliary sleeve **24** extending between a proximal end **26** and a distal end **28**, and the proximal end **26** of the auxiliary sleeve **24** is located in proximity to the proximal end **14** of the respective guide sleeve **12**.

Reference is made herein and hereinafter to a virtual surface **102** reproducing the vertebra **100** of the patient. As known per se, this virtual surface **102** is obtained from the three-dimensional model of the patient's vertebra **100**. A specific virtual surface **102** is therefore uniquely identified for each individual guide device **10**. Moreover, when the guide device **10** is correctly arranged in the coupling configuration, its position is uniquely defined with respect to the virtual surface **102**. Due to the uniqueness of the virtual surface **102** and the uniqueness of the reciprocal position between the same and the guide device **10** in the coupling configuration, some features of the guide device **10** can be defined unambiguously in relation to the virtual surface **102**. In the present discussion, the expressions "in use", "during use" or the like refer to the guide device **10** in the configuration of coupling to the virtual surface **102**.

Since the virtual surface **102** faithfully reproduces the vertebra **100**, in the attached figures it is represented as resting on the vertebra **100** itself and can actually be identified as the real surface of the vertebra **100**, without however introducing ambiguities or errors.

Advantageously, each guide sleeve **12** and the corresponding auxiliary sleeve **24** have a diverging development starting from the respective proximal ends **14**, **26**.

Preferably, each guide sleeve **12** extends along a respective main axis Xp and the respective auxiliary sleeve **24** extends along a respective auxiliary axis Xa. In this case, advantageously, each auxiliary axis Xa intersects the respective main axis Xp.

In accordance with some embodiments of the guide device **10**, each auxiliary axis Xa forms an angle α with the respective main axis Xp.

Preferably, the angle α formed by an auxiliary axis Xa and the respective main axis Xp is comprised between 20° and 60°, even more preferably between 25° and 45°.

If the main axis Xp and the secondary axis intersect, they lie in the same plane and the angle α is immediately identifiable by the skilled person. Vice versa, if there is no plane containing both the main axis Xp and the auxiliary axis Xa (i.e. in the case where these axes are skew), it is possible, for example, to consider by analogy the angle formed by the projections of the axes on a plane perpendicular to the segment that represents the minimum distance between the two axes.

Note that the terms "distal" and "proximal", as used herein, refer to the relative position of an element (e.g. the end of a sleeve) with respect to the virtual surface **102** of the vertebra **100**.

Each guide sleeve **12** houses an insertion duct **30** extending with substantial continuity between the distal end **16** and the proximal end **14**. In other words, the insertion duct **30** extends between a distal opening **32**, formed in the distal end **16** of the guide sleeve **12**, and a proximal opening **34**, formed in the proximal end **14** of the guide sleeve **12**.

Similarly, each auxiliary sleeve **24** houses a service duct **36** extending with substantial continuity between the distal end **28** and the proximal end **26**. In other words, the service duct **36** extends between a distal opening **38**, formed in the distal end **28** of the auxiliary sleeve **24**, and a proximal opening **40**, formed in the proximal end **26** of the auxiliary sleeve **24**.

In accordance with some embodiments (see, for example, FIGS. **6-8**), the proximal opening **40** of the service duct **36** is defined in the wall of the insertion duct **30**, near its proximal end **14**. In these embodiments, the service duct **36** opens into the insertion duct **30**.

In other embodiments (see, for example, FIGS. **1-5**), the proximal opening **40** of the service duct **36** is slightly spaced apart from the proximal opening **34** of the insertion duct **30**.

Both the insertion ducts **30** and the service ducts **36** define respective insertion axes for a tool whose use is preferably planned in detail in the preoperative phase.

Therefore, in each duct **30**, **36**, the distal opening **32**, **38** corresponds to an access opening of a tool, while the proximal opening **34**, **40** faces the patient's vertebra **100**, in the vicinity of the same.

Tools that can be used with the guide device **10** can typically be: a Kirschner wire, a cannulated polyaxial screw, a solid polyaxial screw, a drill, a tapper, a punch, a probe, a marker, a pin. These tools are referred to hereinafter as the "main surgical tools" since it is these that carry out the main phase of the surgical intervention. A main surgical tool **42** is schematically represented in FIGS. **1**, **2** and **5**.

In a known manner, therefore, the diameter of the insertion duct **30** is such that it allows the insertion of a main surgical tool **42**. Depending on the areas of application, the inner diameter of the insertion ducts can be selected from 3-18 mm, 3-12 mm, 3-9 mm, 3-6 mm.

In accordance with the invention, the diameter of the service duct **36** is such that it allows the insertion of a preparatory drill. Depending on the areas of application, the inner diameter of the insertion ducts can be selected from 1.8-4 mm, 2-3 mm. Such a preparatory drill has the task of superficially incising the bone to facilitate the use of the main surgical tool **42**.

In light of the above, the skilled person can readily understand that the main axis Xp of the guide sleeve **12** defines the direction of advancement of the insertion duct **30**, hence of the main surgical tool **42**. Similarly, the auxiliary axis Xa of the auxiliary sleeve **24** defines the direction of advancement of the service duct **36**, hence of the preparatory drill (not shown in the figures). The direction of advancement Xa of the preparatory drill can be advantageously defined during the preoperative planning, most of all to optimally define the angle β at which the preparatory drill approaches the virtual surface **102** of the vertebra **100**. Some considerations on the angle β are given below.

Advantageously, therefore, the auxiliary axis Xa reaches the minimum distance from the main axis Xp in proximity to the virtual surface **102** of the vertebra **100**. Preferably, the auxiliary axis Xa intersects the main axis Xp in proximity to the virtual surface **102** of the vertebra **100**.

Preferably, as can be seen in the cross sections depicted in FIGS. **5** and **8**, the auxiliary axis Xa reaches the minimum distance from the main axis Xp or intersects it, at a point inside the vertebra **100**. In accordance with some embodiments, the auxiliary axis Xa reaches the minimum distance from the main axis Xp or intersects it within 5 mm from the virtual surface **102**.

According to an optional aspect of the present invention, the guide sleeves **12** can be oriented so that the proximal ends **14** are more distant from each other with respect to the distal ends **16**. In other words, the main axes Xp of the guide sleeves **12** are oriented, starting from the respective distal ends **16**, away from each other. Therefore, the guide device **10** according to the present invention preferably has a "diverging" configuration, in which the guide sleeves **12** diverge in the proximal region. Advantageously, this simplifies the positioning of the device **10**, thus reducing the space required for insertion by the surgeon.

As the skilled person can well understand, the orientation of each auxiliary sleeve **24** can be chosen rather freely during the design of the device **10**. In particular, the orientation with respect to the virtual surface **102** of the vertebra **100** can be defined regardless of the direction Xp to be followed by the main surgical tool **42**.

The orientation and positioning of the guide sleeves **12** and the respective auxiliary sleeves **24** are designed during the preoperative phase, by means of computer-aided design tools, on a three-dimensional model of the bone structure. This model is developed from a three-dimensional image obtained, for example, by computerized tomography and/or magnetic resonance of the patient's vertebra **100**. Therefore, each sleeve **12**, **24** is designed so as to uniquely define the direction of the respective axis Xp, Xa with respect to the vertebra **100**.

Preferably, the device **10** is constructed so that each auxiliary axis Xa, in use, forms an angle @ with the portion of the virtual surface **102** of the vertebra **100** on which it is incident, the angle β being favourable to the use of the preparatory drill. The angle @ formed, in use, by each auxiliary axis Xa with the portion of the virtual surface **102** of the vertebra **100** on which it is incident is preferably comprised between 60° and 120°, even more preferably between 75° and 105°.

As mentioned previously, a junction element **22** is provided between the two guide sleeves **12**.

Preferably, the at least one junction element **22** extends transversely to the two guide sleeves **12** to place them in rigid connection with one another. More preferably, the junction element **22** is located in proximity to the distal end **16** of the guide sleeves **12**.

Therefore, such a junction element **22** is a preferably non-straight crosspiece extending between the two guide sleeves **12** to space them apart and keep them firmly in a pre-established mutual position.

Preferably, the guide sleeves **12** are spaced apart from each other by a distance at least suitable to allow the housing of a spinous process **104** of the vertebra **100** to be operated on.

In accordance with some embodiments, the junction element **22** takes an inverted "U" shape that defines therein a seat **44** for housing the spinous process **104** of the vertebra **100**.

According to some embodiments, for example those shown in FIGS. **1-4**, the seat **44** for housing the spinous process **104** is open in the cranial-caudal direction in order to prevent the patient's ligaments from having to be excised before placing the guide device **10** in the coupling configuration (open profile).

Alternatively, for example in the embodiment shown in FIGS. **6-7**, the seat **44** for housing the spinous process **104** can be closed in the cranial-caudal direction by one or more partitions **46** connecting the sides of the junction element **22**, respectively forming a semi-open or closed profile surrounding the spinous process **104**, so as to ensure excellent stability to the guide device **10**.

According to a further optional aspect of the present invention, the junction element **22** preferably comprises a handle **48** suitable to facilitate the surgeon's handling of the device **10**. For instance, the handle **48** can extend from the junction element **22** (see, for example, figures from 2 to 4). Alternatively, the handle **48** can extend similarly to the junction element **22**, joining the two guide sleeves **12** to each other.

In order to promote the stability of the device **10**, it comprises a plurality of support elements **18** preferably arranged near the proximal end **14** of each guide sleeve **12**. Each support element **18** defines a contact area **20** configured for abutting against a specific portion of the virtual surface **102** of the patient's vertebra **100**, in a coupling configuration.

Preferably, this portion is one side of the spinous process **104**, a lamina, an articular process, or a transverse process of the patient's vertebra **100**. As already mentioned for the sleeves, the support elements **18**, and in particular the respective contact areas **20**, are also designed during the preoperative phase, by means of computer-aided design tools, on a three-dimensional model of the bone structure. This model is developed from a three-dimensional image obtained, for example, by computerized tomography and/or magnetic resonance of the patient's vertebra **100**. Therefore, each contact area **20** of the support elements **18** is designed so that it uniquely matches the bone structure of the patient.

In some embodiments, at least one of the support elements **18** is shaped like a hook. In other words, this support element **18** comprises a contact area **20** which is shaped as a whole so as to at least partially encircle a portion of the vertebra **100** and to rest on the vertebra **100** from different directions. By way of example, in the embodiment in figures from 2 to 4, it can be seen that the two support elements **18** are both shaped like a hook, so that each one defines a contact area **20** designed to rest on the arch or lamina of the vertebra **100** partly in the cranial direction and partly in the caudal direction.

Advantageously, this allows a reduced, but particularly firm support area to be obtained.

In certain embodiments, each guide sleeve **12** is also provided with a further contact portion **50**, also located near the proximal end **14** of the guide sleeve **12** and configured to abut against a portion of the virtual surface **102** of the vertebra **100**. Preferably, this contact portion **50**, just like the contact areas **20**, is also shaped complementarily to the virtual surface of the respective portion of the patient's individual vertebra **100**.

The invention achieves the intended objects and attains important advantages.

In fact, the presence of the auxiliary sleeves **24** allows the surgeon to incise the surface of the vertebra **100** by operating along a direction Xa which is more favourable than that of the guide sleeves **12**.

Once the preparatory drill has made the surface incision, the insertion of the main surgical tool **42** is considerably simplified and therefore is not likely to undergo dangerous deviations.

It is clear that the specific features are described in relation to different embodiments of the invention for illustrative and non-limiting purposes. Obviously, a person skilled in the art can make further modifications and variations to the present invention in order to meet contingent and specific requirements. For instance, the technical features described in relation to one embodiment of the invention may be extrapolated from it and applied to other embodiments of the invention. Such modifications and variations also fall within the scope of protection of the invention as defined in the following claims.

The invention claimed is:

1. A disposable guide device for spinal surgery, comprising:

two guide sleeves extending between a proximal end and a distal end for guiding a surgical intervention on a vertebra of a patient;

a plurality of support elements, wherein each support element defines a contact area specifically configured for abutting against a portion of a virtual surface reproducing the vertebra of the patient, in a coupling configuration;

at least one junction element joining the two guide sleeves together, wherein each guide sleeve comprises a respective auxiliary sleeve extending between a proximal end and a distal end the proximal end of the auxiliary sleeve is located in proximity to the proximal end of the respective guide sleeve.

2. The guide device according to claim **1**, wherein each guide sleeve and the respective auxiliary sleeve have a diverging development starting from the respective proximal ends.

3. The guide device according to claim **1**, wherein each guide sleeve extends along a respective main axis and wherein the respective auxiliary sleeve extends along a respective auxiliary axis.

4. The guide device according to claim **3**, wherein each auxiliary axis intersects the respective main axis.

5. The guide device according to claim **3**, wherein each auxiliary axis forms an angle with the respective main axis.

6. The guide device according to claim **5**, wherein the angle is between 20° and 60°.

7. The guide device according to claim **3**, wherein the auxiliary axis reaches a minimum distance from the main axis in proximity to the virtual surface of the vertebra.

8. The guide device according to claim **3**, wherein the auxiliary axis reaches a minimum distance from the main axis or intersects the main axis, at a point inside the vertebra, within 5 mm from the virtual surface.

9. The guide device according to claim **3**, wherein each auxiliary axis forms an angle with the portion of the virtual surface on which the auxiliary axis is incident, the angle being favourable to the use of a preparatory drill.

10. The guide device according to claim **9**, wherein the angle is between 60° and 120.

11. The guide device according to claim **1**, wherein the guide sleeves are oriented so that their proximal ends are further away from each other than the distal ends.

12. The guide device according to claim **1**, wherein at least one of the support elements is shaped like a hook, so as to at least partially encircle a portion of the vertebra.

13. The guide device according to claim **1**, further comprising a handle.

14. The guide device according to claim 6, wherein the angle is between 25° and 45°.

15. The guide device according to claim 10, wherein the angle is between 75° and 105°.

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